

SUPPORT FOR THE AMENDMENTS

A substitute abstract is provided to address the Examiner's objection to the original abstract. Support for the amendment is found in the specification and claims as originally filed.

The present amendment cancels claims 1-15, and adds new claims 16-36.

Support for newly added claim 16 is found at specification page 1, lines 4-8, and page 4, lines 19-24, as well as original claim 1.

Support for newly added claim 17 is found at specification page 8, lines 3-7, as well as original claim 2.

Support for newly added claim 18 is found at specification page 8, lines 8-15.

Support for newly added claims 19-21 is found at specification page 8, lines 19-23, and page 9, lines 15-21.

Support for newly added claims 22-24 is found at specification page 8, lines 24-25, and page 9, lines 1-5 and 15-21, as well as original claim 3.

Support for newly added claim 25 is found at specification page 9, lines 22-25, and page 10, lines 1-5, as well as original claim 4.

Support for newly added claims 26-27 is found at specification page 10, lines 6-25, and page 11, lines 1-5, as well as original claims 5 and 6.

Support for newly added claim 28 is found at specification page 12, lines 17-23, and page 13, line 12.

Support for newly added claims 29-30 is found at specification page 12, lines 7-9, as well as original claims 7 and 8.

Support for newly added claim 31 is found in original claim 8.

Support for newly added claim 32-33 is found at specification page 5, lines 3-19, and page 13, lines 10-17, as well as original claims 9-11.

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Support for newly added claim 34 is found at specification page 11, lines 6-11.

Support for newly added claim 35 is found at specification page 5, lines 20-25, page 6, lines 1-2, page 15, lines 5-7, and page 17, lines 7-21, as well as original claim 12.

Support for newly added claim 36 is found at specification page 6, lines 3-10, page 15, lines 5-7, page 18, lines 15-24, and page 19, lines 1-9, as well as original claim 13.

It is believed that these amendments have not resulted in the introduction of new matter.

REMARKS

Claims 16-36 are currently pending in the present application. Claims 1-15 have been cancelled, and new claims 16-36 have been added, by the present amendment.

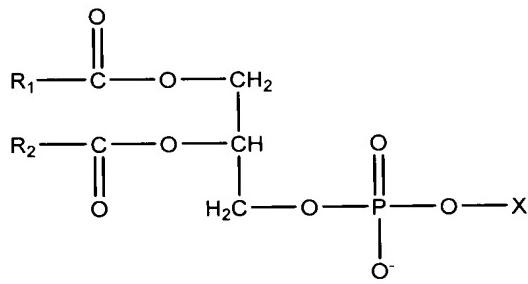
The rejections of now cancelled claims: (1) 1, 5 and 9-11 under 35 U.S.C. § 102(b) as being anticipated over Noble (U.S. Patent 5,484,611); and (2) 1-11 under 35 U.S.C. § 103(a) as being obvious over McCleary (U.S. 2002/0182196) in view of Bydlon (U.S. 2003/0050341), is respectfully traversed with respect to new claims 16-36.

New claim 16 is directed to a composition comprising: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid. Noble, McCleary and Bydlon, when considered alone or in combination, fail to disclose or suggest the presently claimed composition. Even if sufficient motivation and guidance is considered to have been provided by Noble, McCleary and/or Bydlon to arrive at the presently claimed composition, which is not the case, such a case of obviousness is rebutted by a showing of superior properties and secondary considerations. As shown by the comparative experimental data presented in Table 1 of the present specification, the composition in accordance with the present invention remarkably exhibited superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue, as compared to the inferior properties exhibited by the conventional composition.

New claim 16 recites a composition comprising: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid.

Unlike the claimed invention, Noble describes a fatty acid composition comprising phospholipids having fatty acid constituents, wherein the wt. % of the fatty acid constituents present in the phospholipids is as follows: 35.9 wt. % palmitic acid; <1 wt. % palmitoleic acid; 16.2 wt. % stearic acid; 16.4 wt. % oleic acid; 2.2 wt. % linoleic acid; <1 wt. % linolenic acid; 9.6 wt. % arachidonic acid; and 17.7 wt. % docosahexaenoic acid (See e.g., column 3, lines 26-30).

The above-identified fatty acid constituents described in Noble are represented by the R₁ and R₂ moieties of a phospholipid represented by the following general formula:



Therefore, Noble fails to disclose or suggest the claimed composition comprising: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid. As a result, Noble fails to anticipate or render obvious the presently claimed invention.

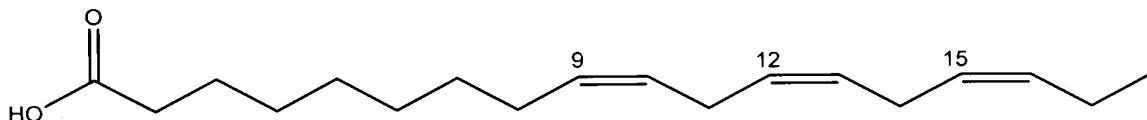
Unlike the claimed invention, McCleary describes a composition for normalizing impaired or deteriorating neurological function comprising: phosphatidyl serine; docosahexaenoic acid; γ -linolenic acid (GLA); and Ginkgo biloba (See e.g., abstract, [0131] and [0177]).

In contrast, the claimed composition comprises: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic

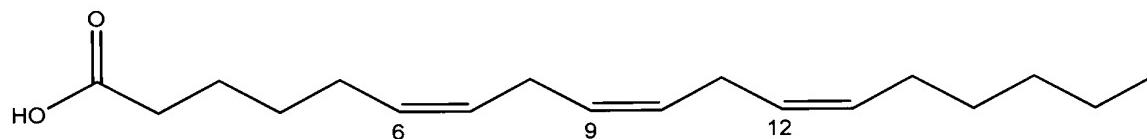
acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid

The *alpha*-linolenic acid of the present invention is *fundamentally different* from the *gamma*-linolenic acid described in McCleary.

The *alpha*-linolenic acid of the present invention has the following structural formula:



In contrast, the *gamma*-linolenic acid of McCleary has the following structural formula:



The *alpha*-linolenic acid of the present invention is obtained from various plant sources including rapeseed (canola), sunflower, soybean, linseed (flaxseed), perilla, egoma and tung.

In contrast, the *gamma*-linolenic acid of McCleary is obtained from different plant sources including evening primrose, blackcurrant seed and borage seed.

The *alpha*-linolenic acid of the present invention is metabolized into eicosapentaenoic acid and docosahexaenoic acid, which have been associated with various beneficial therapeutic effects including reducing the risk of coronary heart disease and treating Alzheimer's disease.

In contrast, the *gamma*-linolenic acid of McCleary is metabolized into thromboxane, which stimulates the aggregation of platelets (thrombosis) and the constriction of blood vessels (hypertension).

Based on the foregoing, a skilled artisan would immediately recognize that the *alpha*-linolenic acid of the present invention is fundamentally different from the *gamma*-linolenic acid of McCleary.

Therefore, McCleary fails to disclose or suggest the claimed composition comprising: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid. As a result, McCleary fails to anticipate or render obvious the presently claimed invention.

Unlike the claimed invention, Bydlon describes a composition for treating cardiovascular system and central nervous system disorders comprising: docosahexaenoic acid; at least one vitamin; and at least one mineral (See e.g., [0008] and [0021]). Bydlon also describes that the docosahexaenoic acid, to be incorporated within the composition, may be obtained from various sources including flaxseed oil (linseed oil), canola oil (rapeseed oil) and sunflower oil, as well as oils and fats from cold-water fish (See e.g., [0024]). It should be mentioned however that while Bydlon describes that fish convert linolenic acid, obtained from ingesting algae, to docosahexaenoic acid, Bydlon fails to describe incorporating α -linolenic acid into the composition (See e.g., [0024]). Accordingly, Bydlon fails to compensate for the deficiencies of McCleary.

Bydlon fails to disclose or suggest the claimed composition comprising: a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and α -linolenic acid and/or an oil comprising α -linolenic acid. As a result, Bydlon likewise fails to anticipate or render obvious the presently claimed invention.

Assuming *arguendo* that sufficient motivation and guidance is considered to have been provided by Noble, McCleary and/or Bydlon to arrive at the presently claimed

composition, which is not the case, such a case of obviousness is rebutted by a showing of superior properties and secondary considerations.

As discussed in the present specification, conventional compositions comprising n-3 polyunsaturated acids, such as docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid, suffer from inferior properties with respect to systemic absorption into blood and tissue (See e.g., page 1, lines 10-25, and page 2, lines 1-4). Accordingly, there has been a long-felt need to provide a composition that exhibits superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue. Based on the limited disclosures of Noble, McCleary and Bydlon, other skilled artisans have failed to discover a solution to this long-felt need.

As shown by the comparative experimental data presented in Table 1 of the present specification, which is reproduced hereinbelow for the Examiner's convenience, Applicants have discovered that superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue are remarkably exhibited by the composition of the present invention.

Table 1

Test Group	DHA content (%) in all fatty acids: n = 5	
	PS-DHA + linoleic acid (safflower oil)	PS-DHA + α -linolenic acid (linseed oil)
Serum	4.24 \pm 0.10	6.60 \pm 0.23
Brain	5.20 \pm 0.17	6.03 \pm 0.12

Specifically the composition in accordance with the present invention remarkably exhibits superior properties with respect to enhanced systemic absorption of an n-3 polyunsaturated acid (e.g., docosahexaenoic acid (DHA)) into blood serum and tissue (e.g., brain), as compared to the inferior properties exhibited by conventional compositions, which do not contain the claimed phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and

eicosapentaenoic acid, in combination with the claimed α -linolenic acid and/or an oil comprising α -linolenic acid.

This evidence clearly demonstrates that a composition in accordance with the present invention remarkable exhibits superior properties with respect enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue, as compared to the inferior properties exhibited by conventional compositions.

Withdrawal of these grounds of rejection is respectfully requested.

The Examiner is respectfully reminded that upon a determination that the product claims drawn to the elected invention are found allowable, method claims drawn to the non-elected invention should be rejoined and examined for patentability, pursuant to MPEP § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).

In conclusion, Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

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